



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/614,490 | 07/11/2000 | Fearghus O'Foghludha | 9105-21-IP | 2050 |

20792 7590 05/30/2003

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

| EXAMINER |
|----------|
|----------|

HARTLEY, MICHAEL G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 05/30/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/614,490

Applicant(s)

O'FOGHLUDHA, FEARGHUS

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1616

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/21/2003 has been entered.

Response to Amendment

The amendment filed 2/18/2003 has been entered. Claims 1 and 5 have been amended.

Applicant's arguments with respect to claims 1 and 3-9 have been considered but are moot in view of the following new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation that "the nuclide is a chemically bound constituent of the polymer chain" was not described in such a way as to reasonably convey to one skilled in the art that the inventors had possession of such as claimed. The reasons for this are two fold.

First, the specification only describes that the nuclide is preferably located in the "backbone" of the polymer, see page 3, lines 23-24. However, being located in the backbone encompasses a different scope and provides a different meaning than in the "chain," as the backbone includes pendent groups, while the chain is specifically limited to the chain of the polymer. Note, the instant specification states "backbone" and not "chain". This is a significant differentiation. For example, the prior art teaches integral sources wherein the polymer "backbone" includes the radionuclide, wherein the radionuclide is

Art Unit: 1616

bonded to a pendant phosphate group (see Pat. 5,873,811 to Wang, No. 19, PTO-1449, column 6, lines 45-56). Thus, the "backbone" includes pendent groups, which are not part of the chain. Applicant asserts this difference in arguing that Suthanthiran (US 5,163,896) does not disclose a nuclide in the chain with the iodine labeled polyamino acids in column 3, which while not in the chain are in the backbone because they are in pendent groups, directly attached to the chain (e.g., part of the backbone).

Second, evidence that applicant did not envision the scope of radionuclide in the "chain" of the polymer is evident from the use of the polymers and nuclides set forth in the claims. For example, the various nuclides listed on page 4 of the specification are not part of the chain of the polymers listed in the specification directly below the nuclides. More specifically, various nuclides, such as I, F, etc., listed in the specification are not capable of being in the polymer chain, per se, as these nuclide are monovalent. Also, the metals listed are only part of the chain in the polyphenylmetallosiloxane polymer.

The dependent claims fall therewith.

Claims 1 and 3-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nuclides in the "chain" wherein C, P and S are in the chain for all of the polymers and for the metals only when the polymer is polyphenylmetallosiloxane, does not reasonably provide enablement for the rest of the nuclides as set forth in claim 4, namely for I, F or Cl for any polymer and for any metal for any polymer other than polyphenylmetallosiloxane. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. As held by ex parte Forman (230 USPQ 546, BdPatApp & Int.) and In re Wands (8 USPQ 2d 1400, CAFC), there are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation.

Amount of guidance present

The specification fails to provide any guidance for preparing polymers having a nuclide in the chain, wherein the nuclide is a monovalent atom, such as, I, F or Cl, because there is no guidance in the

Art Unit: 1616

specification on how to incorporate a monovalent atom into a polymer chain which would necessitate divalency, as any monovalent atom would necessarily be a pendent group or end group, which is also a pendent group. Also, the specification only provide guidance on the use of metals in the chain when the polymer is a polyphenylmetallosiloxane, as this is the only polymer listed which may contain a metal in the chain.

Absence of working example

The specification only provides a limited number of working examples, specifically only polyphenylmetallosiloxane polymers, wherein the metal may be in the chain and which is enabled. However, there are no examples of making polymers having I, F, Cl in the chain or the use of other polymers, as listed in claim 3, having a metal in the chain.

Nature of invention

The nature of the invention is a method of preparing a polymer having a nuclide in the chain. However, the claims recite various nuclides being in the polymer chain, but said nuclide is not a part of the polymer chain and there is no clear guidance on how such a nuclide can be incorporated into a polymer chain.

State of the prior art

The state of the prior art in making various polymers, i.e., polyurethane, nylon, polypropylene, etc., having an I, FI, Cl, or a metal in the polymer chain is not well understood, as neither these atoms are part of the polymer chain nor is it chemically possible to incorporate such atoms into such polymer chains. For example, since F, I and Cl are monovalent, these atoms would always be a pendent group (in the backbone of the chain or the end of the polymer). Also, the other polymers, excluding polyphenylmetallosiloxane, do not include metals in the chain or atoms which can be covalently bound to metals in such a chain.

Relative skill of those in the art

The relative state of those in the art would provide guidance on the preparation of various nuclides in the polymers as claimed as there is no clear method of incorporating an atom into a polymer chain when the polymer chain does not contain such an atom.

Art Unit: 1616

Breadth of the claims

The claims are broad, wherein not only can almost any nuclide be used, but various different polymers. However, since the nuclide must be in the chain, it is unclear how nuclides which are not part of the named polymer chains be part of the chain.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, the recitation of "Cl" is indefinite because there is no nuclide which has this letter code. It is unclear if this is a typo and is meant to be Cl for chlorine.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Suthanthiran (US 5,163,896).

Suthanthiran discloses an integral source material (i.e., a radioactive seed) comprising a nuclide wherein the nuclide is chemically bound to a polymer, see column 3-4. For example, the nuclide may be

Art Unit: 1616

³²P labeled polynucleotides, wherein the phosphorus would be in the chain of the polymer, see column 4, lines 4-9. The limitation of "activated by exposure to radiation" is essentially, a "product-by-process" limitation, which fails to specifically limit the device to differentiate over the Suthanthiran, since this patent discloses an integral source having all of the same components as claimed, i.e., a nuclide which is a chemically bound constituent of a polymer chain of the integral source material, which is part of a radioactive enclosure, i.e., a radioactive seed. In product-by-process claims, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The fact the nuclide was made by a process of being "activated by exposure to radiation" would not give rise to a product which is different from Suthanthiran, since a radionuclide is a radionuclide, regardless of how it is obtained (however, most radionuclides are prepared by exposure to radiation). The radioactive seeds include a rectangular substrate, see figure 1, as well as, radioactive walls, see figure 3 and may have both flexible (see column 6, lines 22-65) and rigid enclosures, such as, a titanium capsule, see column 7, lines 35+.

Claims 1, 3, 4 and 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Grunze (US 2002/0054851).

Grunze discloses an integral source, i.e., an artificial implant, comprising a nuclide that is a constituent in the polymer chain (the P is in the polymer chain), such as, a fluorine containing polyphosphazene, see paragraphs [0013] to [0016]. For the reasons set forth above, the limitation, "activated by exposure to radiation" does not differentiate over the prior art, as this a step in the method of preparation. The integral source material is using in implants, stents, etc., and is contained in plastics, metals, alloys, ceramics, etc., which would be both flexible or rigid, rectangular in shape, (i.e., a stent) and since the radiolabeled polymer is used as a coating, such devices would have radioactive walls, see paragraphs [0021]-[0026].

Art Unit: 1616

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Suthanthiran (US 5,163,896) or Grunze (US 2002/0054851) in view of either one of Park (US 6,152,869) or Good (US 5,342,283).

Suthanthiran and Grunze disclose an integral source material comprising a nuclide, wherein the nuclide is a constituent in the polymer chain, as set forth above.

Suthanthiran and Grunze fail to specifically disclose that the nuclide is one that is activated (e.g., made radioactive) after preparation of the source and that the source has checkerboard form (claim 5). However, it is well known in the art of radioactive source, that starting with an activatable isotope provides increased safety and preparation as shown by Park and Good and that checkerboard form is known format, as shown by Park.

Park discloses that the nuclide can be one that is activatable by irradiation to provide the advantage of preparing the source without having to manipulate radioactive material, thereby increasing both safety and ease of preparation, e.g., column 6, lines 30-48. Park also teaches that the stents may be in a checkerboard, see figures 2 and 3.

Good discloses radioactive source which may comprise various nuclides and teaches the use of nonradioactive isotopes which can be later activated into radioactive form as equivalents to radionuclides, e.g., to provide easier preparation, see column 3, lines 4+.

It would have been obvious to one of ordinary skill in the art to use a nuclide which is activatable in the radioactive polymer based radioactive source disclosed by Suthanthiran or Grunze because it is well known in the art that the use of a radioactivatable nuclide (e.g., a radionuclide precursor) may be

Art Unit: 1616

used in a radioactive source as equivalent to radionuclides for easier and safer preparation. One of ordinary skill in the art would have been motivated to use an activatable nuclide because it provides the clear advantages of increased safety in the preparation of the source, as well as, increased shell life (without radioactive decay concerns). Further, it would have been obvious to form the stents in a checkerboard form because the prior art teaches that this is a known and preferred means of distributing radioactive material on such stents, as shown by Park.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,547,816. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the '816 patent is directed to an integral source having a subspecies of polymer, i.e., polyarylene ether phosphine oxide polymer and a subspecies of nuclide, phosphorus, which falls entirely within the scope of claim 1 in the application, or in other words claim 1 is anticipated by the claim 1 of the '816 patent. Also, the physical limitations set forth in claims 6-9 are obvious modifications of the integral source, as these limitations are part of the definition of "integral source" as contained in claim 1 of the '816 patent, as can be seen by the figures defining said integral source in the patent.

Conclusion

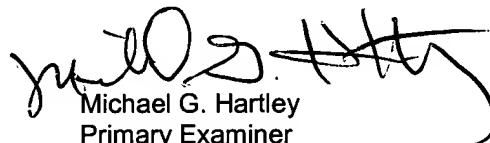
No claims are allowed at this time.

Art Unit: 1616

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Michael G. Hartley
Primary Examiner
• Art Unit 1616

MH
May 29, 2003